Exhibit D

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

MODERNATX, INC. and MODERNA US, INC., Plaintiffs, v. PFIZER INC., BIONTECH SE, BIONTECH MANUFACTURING GMBH, and BIONTECH US INC., Defendants.	C.A. No. _________ **JURY TRIAL DEMANDED**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs ModernaTX, Inc. and Moderna US, Inc. (collectively, "Moderna" or the "Company"), by and through their attorneys, hereby allege for their patent infringement Complaint against Defendants Pfizer Inc. ("Pfizer"), BioNTech SE, BioNTech Manufacturing GmbH, and BioNTech US Inc. ("BioNTech US," together with BioNTech SE and BioNTech Manufacturing GmbH, "BioNTech") as follows:

NATURE OF THE CASE

A. Moderna Was Founded in 2010 on the Promise of Developing mRNA Technology to Create a New Generation of Transformative Medicines

1. Just twelve years ago, messenger RNA ("mRNA") medicines were a new and unproven technology. Although many doubted that this technology could ever be used to treat or prevent disease, Moderna recognized early on that it had great potential to improve patients' lives. Since Moderna's founding in 2010 in Cambridge, Massachusetts, the Company has been singularly focused on making mRNA medicines a reality through substantial investment and years of research and development.

60. The ’574 patent claims Moderna’s mRNA platform technology, which utilizes mRNA encoding for a polypeptide that comprises a modified uracil, including 1-methylpseudouridine, in a lipid nanoparticle formulation. The ’574 patent claims both methods of producing a polypeptide of interest and pharmaceutical compositions.

61. Moderna practices the ’574 patent through its Spikevax® vaccine, and Moderna marks Spikevax® with a reference to its patent marking website (https://www.modernatx.com/patents [https://perma.cc/B6AG-6URD]), which identifies the ’574 patent for Spikevax®.

B. Coronavirus Vaccines

62. Before COVID-19 first emerged, Moderna made significant breakthroughs in the development of coronavirus vaccines. Coronaviruses are a class of viruses that are enveloped in a protein shell that is covered on the surface by a “spike” protein. A coronavirus spike protein allows the virus to attach to and infect host cells.

63. When another coronavirus, MERS, first emerged in the mid-2010s, Moderna carefully studied, designed and tested a vaccine for MERS. The MERS vaccine that Moderna developed was based on mRNA encoding for the virus’s spike protein. However, coronavirus spike proteins are large molecules, and no one had previously developed an mRNA vaccine targeting an antigen protein of that size before.

64. Moderna was the first to discover that using mRNA encoding for a full-length coronavirus spike protein in a lipid nanoparticle formulation was highly effective at producing neutralizing antibodies to the coronavirus. Moderna’s research showed that its coronavirus vaccine produced neutralizing antibodies that prevented infection and confirmed that targeting the spike protein was a successful vaccine design that could be applied to other coronaviruses. Moderna’s ’600 and ’127 patents describe and claim the results of that research.

65. When COVID-19 first emerged, this prior research allowed Moderna to design a vaccine for SARS-CoV-2 in record time. Moderna used the coronavirus vaccine design described and claimed in the '600 and '127 patents to develop an mRNA vaccine for COVID-19 by using mRNA encoding for the full-length spike protein for SARS-CoV-2 in a lipid nanoparticle formulation. Although Pfizer and BioNTech initially considered alternative vaccine designs, they ultimately chose to follow Moderna's path of using mRNA encoding for the full-length spike protein of SARS-CoV-2—the exact same design used in Moderna's Spikevax®.

66. The '600 patent is titled "Betacoronavirus mRNA vaccine." The '600 patent names as inventors Moderna scientists Giuseppe Ciaramella and Sunny Himansu. The '600 patent claims priority to provisional patent applications filed in October 2015 and a PCT application filed on October 21, 2016. The '600 patent issued on July 7, 2020, and is assigned to Moderna. A true and correct copy of the '600 patent is attached as Exhibit 2.

67. The '600 patent claims compositions comprising mRNA comprising an open reading frame encoding a betacoronavirus S protein or S protein subunit formulated in a lipid nanoparticle.

68. Moderna practices the '600 patent through its Spikevax® vaccine, and Moderna marks Spikevax® with a reference to its patent marking website (https://www.modernatx.com/patents [https://perma.cc/B6AG-6URD]), which identifies the '600 patent for Spikevax®.

69. The '127 patent is titled "Betacoronavirus mRNA vaccine." The '127 patent names as inventors Moderna scientists Giuseppe Ciaramella and Sunny Himansu. The '127 patent claims priority to provisional patent applications filed in October 2015 and a PCT application filed on October 21, 2016. The '127 patent issued on March 2, 2021, and is assigned to Moderna. A true and correct copy of the '127 patent is attached as Exhibit 3.

70. The '127 patent claims methods of administering to a subject mRNA comprising an open reading frame encoding a betacoronavirus S protein or S protein subunit formulated in a lipid nanoparticle to induce in the subject an immune response to the S protein or S protein subunit, wherein the lipid nanoparticle comprises certain specified percentages of ionizable cationic lipid, neutral lipid, cholesterol, and PEG-modified lipid.

71. The administration of Moderna's Spikevax® in accordance with its approved package insert practices the methods claimed in the '127 patent.

PFIZER AND BIONTECH'S COVID-19 VACCINE

72. Prior to the emergence of COVID-19, Pfizer and BioNTech had begun researching an mRNA vaccine for influenza, but lacked Moderna's expertise in developing mRNA vaccines for coronaviruses and other infectious diseases. Indeed, BioNTech's CEO, Uğur Şahin, had stated that infectious disease targets were "not a priority" for his company before COVID-19.[9] Upon information and belief, Pfizer lacked any candidates in clinical trials using mRNA technology before COVID-19, and BioNTech did not have any such candidates in clinical trials for infectious diseases.[10] By contrast, Moderna had six mRNA candidates for infectious diseases in clinical trials by the time COVID-19 arrived.

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[9] Asher Mullard, *COVID-19 Vaccine Success Enables a Bolder Vision for mRNA Cancer Vaccines, Says BioNTech CEO*, 20 Nature Revs.: Drug Discovery 500 (June 17, 2021), *available at* https://www.nature.com/articles/d41573-021-00110-x ("[Q.] Prior to the pandemic, your first priority was cancer therapies. How much will you now focus on infectious disease vaccines? [A.] We were always interested in infectious diseases, but they were not a priority.") [https://perma.cc/GV6C-UD74].

[10] BioNTech, *Fourth Quarter and Full Year 2019 Corporate Update and Financial Results* 10-11 (Mar. 31, 2020), https://investors.biontech.de/static-files/a718a9ec-53cd-42b6-a6e0-8dd21ca4d907.

duction at Pfizer's facility in Andover, Massachusetts "to support the continued supply of Comirnaty in the European Union."[14] Pfizer and BioNTech have also made clear that they intend to sell additional booster doses of Comirnaty®. For example, on March 29, 2022, the FDA authorized certain people to receive a second booster dose of Pfizer and BioNTech's COVID-19 vaccine.[15] Pfizer and BioNTech actively promote the use of booster doses for their COVID-19 vaccine, including through their website for Comirnaty®: https://www.comirnaty.com/booster-dose/ [https://perma.cc/7WHG-LZ3B].

82. In the face of that ongoing infringement, Moderna filed this lawsuit so that it may obtain fair compensation for Pfizer and BioNTech's continued use of Moderna's patented technologies. That fair compensation will translate into an opportunity for Moderna to reinvest in its leading mRNA platform that allowed both Moderna and Pfizer/BioNTech to address the COVID-19 pandemic. Indeed, were Pfizer and BioNTech allowed to freely copy Moderna's patented technology for their own benefit, the next generation of biotech startups would lose their ability to rely on the patent system that is the bedrock upon which future medicines will be discovered.

COUNT I – INFRINGEMENT OF THE '574 PATENT

83. Moderna incorporates each of the above paragraphs 1-82 as though fully set forth herein.

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[14] European Medicines Agency, *Increase in Manufacturing Capacity for COVID-19 Vaccines from Janssen, Moderna, and BioNTech/Pfizer* (Dec. 16, 2021), https://www.ema.europa.eu/en/news/increase-manufacturing-capacity-covid-19-vaccines-janssen-moderna-biontech-pfizer [https://perma.cc/43DL-YXK9].

[15] Pfizer, Inc., Press Release, Pfizer and BioNTech Receive Expanded U.S. Emergency Use Authorization for an Additional COVID-19 Vaccine Booster in Individuals Aged 50 Years and Older (Mar. 29, 2022), https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-receive-expanded-us-emergency-use [https://perma.cc/BRL9-NX8P].

84. Upon information and belief, Defendants have directly infringed and continue to directly infringe one or more of the claims of the ’574 patent, either literally or under the doctrine of equivalents, by making, using, selling, offering for sale, and/or importing Comirnaty® in the United States and in this District without authority, in violation of 35 U.S.C. § 271(a).

85. Upon information and belief, the use of Comirnaty® in accordance with its approved package insert and/or emergency use authorization infringes one or more of the claims of the ’574 patent. Defendants have induced infringement and continue to induce infringement of one or more of the claims of the ’574 patent, either literally or under the doctrine of equivalents, by encouraging others, including but not limited to healthcare providers and patients, to make and use Comirnaty® in the United States and in this District in a manner that would directly infringe the ’574 patent. Defendants have intentionally encouraged and will continue to intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the ’574 patent and with knowledge that their acts are encouraging infringement, in violation of 35 U.S.C. § 271(b).

86. Upon information and belief, Comirnaty® constitutes a material part of the invention of one or more claims of the ’574 patent and is not a staple article or commodity of commerce suitable for substantial noninfringing use. Defendants have contributorily infringed and continue to contributorily infringe one or more of the claims of the ’574 patent, either literally or under the doctrine of equivalents, by promoting the making and use of Comirnaty® in accordance with its approved package insert and/or emergency use authorization in the United States and in this District by others, including but not limited to healthcare providers and patients, and knowing that Comirnaty® is especially made or especially adapted for use to infringe the ’574 patent, in violation of 35 U.S.C. § 271(c).

87. Upon information and belief, Defendants have infringed or will infringe one or more of the claims of the ’574 patent, either literally or under the doctrine of equivalents, in violation of 35 U.S.C. § 271(f), including by supplying the global market for Comirnaty® with components, such as mRNA, manufactured in the United States.

88. Comirnaty® satisfies each and every element of one or more claims of the ’574 patent. Defendants’ actions with respect to Comirnaty® have infringed, induced infringement, or contributorily infringed at least claims 1-4 and 6-10 of the ’574 patent.

89. For example, claim 2 of the ’574 patent is representative and recites:

> A pharmaceutical composition comprising:
>
> > a plurality of lipid nanoparticles comprising a cationic lipid, a sterol, and a PEG-lipid,
> >
> > wherein the lipid nanoparticles comprise an mRNA encoding a polypeptide,
> >
> > wherein the mRNA comprises one or more uridines, one or more cytidines, one or more adenosines, and one or more guanosines and wherein substantially all uridines are modified uridines.

90. Comirnaty® is a pharmaceutical composition comprising a plurality of lipid nanoparticles comprising a cationic lipid, a sterol, and a PEG-lipid, wherein the lipid nanoparticles comprise an mRNA encoding a polypeptide, wherein the mRNA comprises one or more uridines, one or more cytidines, one or more adenosines, and one or more guanosines and wherein substantially all uridines are modified uridines.

91. For example, Section 12 of the package insert for Comirnaty® states that “[t]he nucleoside-modified mRNA in COMIRNATY is formulated in lipid particles, which enable delivery of the mRNA into host cells to allow expression of the SARS-CoV-2 S antigen.” Section 11 of the package insert for Comirnaty® states that “[e]ach 0.3 mL dose of the COMIRNATY . . .

109. Comirnaty® satisfies each and every element of one or more claims of the '600 patent. Defendants' actions with respect to Comirnaty® have infringed, induced infringement, or contributorily infringed at least claims 1-2, 4-6, 8-12, 16-17, 20-21, and 26 of the '600 patent.

110. For example, claim 1 of the '600 patent is representative and recites:

> A composition, comprising:
>
> > a messenger ribonucleic acid (mRNA) comprising an open reading frame encoding a betacoronavirus (BetaCoV) S protein or S protein subunit
> >
> > formulated in a lipid nanoparticle.

111. Comirnaty® is a composition comprising a messenger ribonucleic acid (mRNA) comprising an open reading frame encoding a betacoronavirus (BetaCoV) S protein or S protein subunit formulated in a lipid nanoparticle.

112. For example, Section 11 of the package insert for Comirnaty® states that "[e]ach 0.3 mL dose of COMIRNATY . . . contains 30 mcg of a nucleoside-modified messenger RNA (mRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2." Ex. 7 at 19. Section 12 of the package insert for Comirnaty® states that "[t]he nucleoside-modified mRNA in COMIRNATY is formulated in lipid particles, which enable delivery of the mRNA into host cells to allow expression of the SARS-CoV-2 S antigen." Ex. 7 at 20. The "SARS-CoV-2 S antigen" encoded by the mRNA in Comirnaty® is a betacoronavirus S protein.

113. Defendants promote the use of Comirnaty® to infringe one or more claims of the '600 patent. For example, Sections 1 and 2 of the package insert for Comirnaty® instruct how to use the vaccine.

114. Defendants further promote the use of Comirnaty® booster shots to infringe one or more claims of the '600 patent. For example, among other things, Pfizer and BioNTech maintain

to contributorily infringe one or more of the claims of the '127 patent, either literally or under the doctrine of equivalents, by promoting the making and use of Comirnaty® in accordance with its approved package insert and/or emergency use authorization in the United States and in this District by others, including but not limited to healthcare providers and patients, and knowing that Comirnaty® is especially made or especially adapted for use to infringe the '127 patent, in violation of 35 U.S.C. § 271(c).

126. Upon information and belief, Defendants have infringed or will infringe one or more of the claims of the '127 patent, either literally or under the doctrine of equivalents, in violation of 35 U.S.C. § 271(f), including by supplying the global market for Comirnaty® with components, such as mRNA, manufactured in the United States.

127. The use of Comirnaty® as instructed in its package insert satisfies each and every element of one or more claims of the '127 patent. Upon information and belief, Defendants and others, including but not limited to healthcare providers and patients, have used Comirnaty® in the United States and in this District as instructed in Comirnaty®'s package insert to practice the methods claimed in the '127 patent. Defendants' actions with respect to Comirnaty® have infringed, induced infringement, or contributorily infringed at least claims 1-3, 6-9, 11-13, 17-18, and 20 of the '127 patent.

128. For example, claim 1 of the '127 patent is representative and recites:

> A method comprising administering to a subject
>
> > a messenger ribonucleic acid (mRNA) comprising an open reading frame encoding a betacoronavirus (BetaCoV) S protein or S protein subunit
> >
> > formulated in a lipid nanoparticle
> >
> > in an effective amount to induce in the subject an immune response to the BetaCoV S protein or S protein subunit

> wherein the lipid nanoparticle comprises 20-60 mol% ionizable cationic lipid, 5-25 mol% neutral lipid, 25-55 mol% cholesterol, and 0.5-15 mol% PEG-modified lipid.

129. The use of Comirnaty® as instructed in its package insert is a method comprising administering to a subject a messenger ribonucleic acid (mRNA) comprising an open reading frame encoding a betacoronavirus (BetaCoV) S protein or S protein subunit formulated in a lipid nanoparticle in an effective amount to induce in the subject an immune response to the BetaCoV S protein or S protein subunit wherein the lipid nanoparticle comprises 20-60 mol% ionizable cationic lipid, 5-25 mol% neutral lipid, 25-55 mol% cholesterol, and 0.5-15 mol% PEG-modified lipid.

130. For example, Section 2.2 of the package insert for Comirnaty® instructs users to "[a]dminister a single 0.3 mL dose of COMIRNATY intramuscularly." Ex. 7 at 6. Section 11 of the package insert for Comirnaty® states that "[e]ach 0.3 mL dose of COMIRNATY . . . contains 30 mcg of a nucleoside-modified messenger RNA (mRNA) encoding the viral spike (S) glycoprotein SARS-CoV-2." Ex. 7 at 19. Section 12 of the package insert for Comirnaty® states that "[t]he nucleoside-modified mRNA in COMIRNATY is formulated in lipid particles, which enable delivery of the mRNA into host cells to allow expression of the SARS-CoV-2 S antigen." Ex. 7 at 20. The "SARS-CoV-2 S antigen" encoded by the mRNA in Comirnaty® is a betacoronavirus S protein. Section 12 of the package insert for Comirnaty® further states that "[t]he vaccine elicits an immune response to the S antigen, which protects against COVID-19." *Id.* Section 11 of the package insert for Comirnaty® further states that "[e]ach 0.3 mL dose of the COMIRNATY . . . also includes the following ingredients: lipids (0.43 mg ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.05 mg 2-(polyethylene glycol 2000)-N,N-ditetradecylacetamide, 0.09 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.2 mg cholesterol), 0.01 mg potas-

e. A declaration that this is an exceptional case and an award to Moderna of its attorneys' fees, costs, and expenses, pursuant to 35 U.S.C. § 285; and

f. Such other relief as this Court may deem just and proper, except Moderna does not seek injunctive relief against Comirnaty®.

DEMAND FOR JURY TRIAL

Moderna respectfully requests a trial by jury on all issues so triable in accordance with Rule 38 of the Federal Rules of Civil Procedure.

Date: August 26, 2022

Respectfully submitted,

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